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FDA sends Claritin over the counter

Popular allergy medicine to be available without prescription

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WASHINGTON (CNN) -- Claritin, the nation's top-selling allergy drug, will soon be available on U.S. store shelves at a cost that could be below what some Americans are now paying for prescriptions of the drug, even when insurance picks most of the cost.

Claritin, a non-sedating antihistamine made by the pharmaceutical company Schering-Plough, was approved for over-the-counter use by the Food and Drug Administration Wednesday.

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The drug does not cause drowsiness like some over-the-counter antihistamines and is already approved for over-the-counter allergy relief and hives in 33 countries, including Canada and Britain.

In Canada, consumers pay about \$11 for a month's supply, compared to the average \$17-a-month co-payment for U.S. patients with insurance coverage. Without insurance, a month's prescription costs about \$60 in the United States.

"By making it easier to get this widely-used drug, today's action will enable many people to get less-sedating, effective relief for their allergy symptoms more quickly and at a lower cost," said Dr. Mark B. McClellan, FDA commissioner. "This approval reflects FDA's commitment to bringing prescription drugs to the over-the-counter market when they can be safely used without a prescription."

Claritin has been available by prescription in the United States since 1993. It is sold in five formulas -- tablets, syrup, redi-tabs (quick dissolving tablets) and 12- and 24-hour Claritin-D, which has a decongestant added. So far this year, the Claritin products have netted \$1.5 billion in sales in the United States.

Claritin's road to over-the-counter status has not been without bumps. In an unprecedented move to cut prescription drug costs, WellPointe HealthWorks in California petitioned the FDA last year to force the

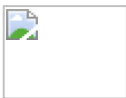
makers of the three popular antihistamines -- Claritin, Allegra and Zyrtec -- to make their allergy medications available over the counter. Action on Allegra and Zyrtec is still pending.

Originally against the idea, Schering-Plough announced in March that it would make Claritin available for treatment of seasonal allergies without prescription.

The company's decision was probably influenced by the fact that the drug's patent is set to expire, opening the drug to generic competition. U.S. marketing exclusivity ends in December.

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